REMARKS/ARGUMENTS

Reconsideration of this application, as amended, is respectfully requested.

Claims 1-41 are pending in the present application.

Of these claims, claims 7-11, 14-17, 21-26 and 30-41 have been withdrawn from consideration. Claims 1-6, 12, 13, 18-20 and 27-29 have been examined in the present Office Action and have been rejected. The Examiner acknowledged our claim for domestic priority under 35 U.S.C. 119(e).

ELECTION/RESTRICTIONS

The Examiner requested restriction to the following groups: Group I (claims 1-29), drawn to the compounds of formula I wherein R_4 is alkyl-het or R_3 and R_4 are taken together with N to form het, the compositions and methods of use; Group II (claims 1-29), drawn to the compounds of formula I wherein R_4 is hydrogen or alkyl-NR_5R_6, the compositions and methods of use; Group III (claims 30-36 and 39), drawn to the methods of treatment of glucocorticoid receptor mediated diseases comprising administrating the compounds and another pharmaceutical agent; Group IV (claim 37), drawn to a kit; Group V (claim 38), drawn to a method of inducing weight loss; and Group VI (claims 40 and 41), drawn to a method of treating an inflammatory disease.

According the Examiner, Groups I-II are directed to structurally dissimilar compounds such that the variables created by varying the definitions of R_3 and R_4 do not belong to a recognized class of chemical compounds in the art, and references anticipating one invention would not render obvious the others. Thus, the Examiner concluded separate searches in the literature as well as in the U.S. Patent Classification System would be required. The Examiner has also stated that inventions I-II and III-IV are related as product and process of use, in the instant case, more than one use exists for compounds of Group I as evidenced by claims 30-41 drawn to a variety of diverse uses.

The Examiner acknowledged the Applicants' election of Group II, claims 1-29 (with traverse) and requested an affirmation of this election in replying to the Office Action. In order to expedite prosecution of the present application, Applicants hereby confirm the election of Group II (claims 1-29, the compound of formula I wherein R_4 is hydrogen or alkyl-NR_5R_6, the compositions and methods of use) and withdraws the traverse to the

restriction/election requirement. Applicants have canceled the non-elected subject matter, including claims 7-11, 14-17, 21-23, 25-26 and 30-41, without prejudice to the filing of a divisional application to the non-elected subject matter. However, Applicants believe that the Examiner's withdrawal of claim 24 is in error because it falls within Group II. Therefore, Applicants have retained claim 24 and respectfully request the Examiner's reconsideration of its inclusion in Group II.

With the above amendments, claims 1, 2, 27 and 29 have been amended; claims 3-6, 12-13, 18-20, 24, and 29 have been retained; and claims 7-11, 14-17, 21-23, 25-26, 28 and 30-41 have been canceled. Support for these amendments is in the specification as filed and as detailed below. Therefore, entry of these amendments is respectfully requested.

Improper Markush Group

The Examiner has objected to claims 1-3 as being an improper Markush grouping on the ground that the recited compounds, while possessing a common utility, present a variable core by varying the definitions of R_3 and R_4.

As noted above, Applicants have amended R_3 and R_4 to the definition set forth in Group II. Therefore, Applicants assert that they have overcome this objection and respectfully request its withdrawal.

CLAIM REJECTIONS – 35 USC § 112, FIRST PARAGRAPH

Claims 1-6 and 27-29 have been rejected under 35 USC §112, first paragraph, because the specification, while being enabling for preparation of compounds wherein R_2 is alkyl or phenyl, does not reasonably provide enablement for preparation and use of compounds wherein R_2 is a functional group other than the above specified functional groups. The Examiner stated that the specification does not enable any person skilled in the art to practice the invention commensurate in scope with these claims.

Applicants have provided support for the preparation of compounds wherein R_2 is a functional group other than alkyl or phenyl as filed, e.g., in the Summary of Invention, at page 6, lines 8-11; page 7, lines 5-6; page 9, lines 13-14, lines 19-20 and lines 26-27. Applicants have also provided descriptions of the processes for preparing the compounds of the present invention wherein R_2 is a functional group other than alkyl or phenyl in the specification as filed, e.g., in Scheme A at page 18; page 19, lines 8-15; and page 20, lines 4-5; in Scheme B at page 22; page 23, lines 1-9, and lines 26-34. In addition, Applicants have cited many scientific literature references which further describe how to make the

compounds wherein R_2 can be a functional group other than alkyl or phenyl, including Frances, A. Carey, Advanced Organic Chemistry, 2nd ed., Part A, Chapter 5.6, 1984. Therefore, Applicants believe that one of ordinary skill in the art would readily be able to prepare and use the compounds of the present invention, wherein R_2 is alky, phenyl or other specified functional group, and respectfully request that this rejection be withdrawn.

Applicants have also provided support for the treatment of the specific glucocorticoid receptor-mediated diseases or conditions with the description of the hosts, dosages and modes of administration for the compounds of formula I in the present specification as filed, e.g., at page 15, lines 28-31; at page 29, line 21, to page 31, line 9; at page 37, line 9, to page 43, line 3. Applicants has also provided a description of the relevant assays in further support of the use of compounds of the present invention, at page 43, line 4, to page 47, line 16.

In addition, Applicants would remind the Examiner, as set forth in the recent Examination Guidelines, a specification that contains a teaching of the manner and process of making and using the invention in terms that correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112, unless there is reason to doubt the objective truth of the statements contained therein, which must be relied on for enabling support. In re Marzocchi, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). The burden is on the Examiner to come forth with evidence to establish a *prima facie* case of non-enablement. Ex parte Hitzeman, 9 U.S.P.Q.2d 1801, 1822 (Pat. Off. Bd. App. 1988); In re Armbruster, 185 U.S.P.Q. 152, 153 (C.C.P.A. 1975); In re Marzocchi, 169 USPQ at 370.

Applicants would submit that the Examiner has not met this burden. As noted above, Applicants are treating specific medical conditions, which are glucocorticoid receptor mediated, and which are well recognized and treated in the medical and patent literature, and which are defined and exemplified in the specification as filed. Applicants submit that the present specification, as filed, clearly supports and enables how to make and how to use the compounds of the present invention. Therefore, with the above amendments and the enabling disclosure in the specification, as filed, Applicants believe that this rejection of claims 1-6, 27 and 29 under 35 USC §112, first paragraph, has been overcome and respectfully request that this rejection be withdrawn.

Claims 1, 2, and 27 have also been rejected under 35 U.S.C. § 112, first paragraph. The Examiner stated that the scope of "prodrug" is not adequately enabled.

Applicants believe that one of ordinary skill in the art would readily understand the term "prodrug". However, in order to expedite prosecution of the present application, claims 1, 2, and 27 have been amended to delete this term from the claims.

According to the Examiner, claim 27, along with claims 28-29, are interpreted to include any and all disorders associated with glucocorticoid receptor-mediated mode of action and the specification reads on any and all diseases such as obesity, diabetes, depression, anxiety and neurodegeneration.

In order to expedite prosecution of the present application, claim 27 has been amended to include the specific diseases described in claim 28, and claim 28 has been canceled. Therefore, Applicants assert that they have overcome this rejection under 35 U.S.C. § 112, first paragraph, and respectfully request its withdrawal

CLAIM REJECTIONS – 35 USC § 112, SECOND PARAGRAPH

Claim 27 has also been rejected under 35 USC §112, second paragraph, as being indefinite, because no one particular disorder is recited and the claim language may read on diseases not yet fully understood to be affected by glucocorticoid receptor modulation.

In order to expedite prosecution of the present application, claim 27 has been amended to include the specific diseases described in claim 28, and claim 28 has been canceled. Therefore, Applicants assert that they have overcome this rejection under 35 U.S.C. §112, second paragraph, and respectfully request its withdrawal

CLAIM REJECTIONS – DOUBLE PATENTING

Claims 1-6, 12, 13, 18-20, and 27-29 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9, 10, 62, and 73 of copending Application No. 10/080,174. According to the Examiner, there are overlapping subject matter, in particular, when the reference compound is of formula II wherein R_{10} is –O-Z-C(O)-$NR_{12}R_{13}$ wherein R_{12} and R_{13} is alkyl.

Applicants would like to point out that the claimed compounds of formula I wherein R_4 is hydrogen or –(C_2-C_5)alkyl-NR_5R_6, as amended, are patentably distinct from the reference compound of formula II wherein R_{10} is –O-Z-C(O)-$NR_{12}R_{13}$ wherein R_{12} and R_{13} is alkyl. As such, Applicants believe that the claims in the present invention do not overlap with the claims in the reference pending patent application, as stated by the Examiner.

However, once allowable subject matter has been found, and if a valid obviousness type double patenting rejection is maintained, Applicants may be willing to timely file a terminal disclaimer in compliance with 37 CFR 1.321(c) in order to expedite prosecution of the present application.

On the basis of the above amendments and remarks, reconsideration of this application, as amended, and its early allowance, are respectfully requested.

Respectfully submitted,

Date: August 25, 2003

Martha A. Gammill
Attorney for Applicants
Reg. No. 31,820

Pfizer Inc.
Patent Department, MS8260-1611
Eastern Point Road
Groton, Connecticut 06340
(860) 441-5940

Attachments:
Petition for Extension of Time